DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 1, 2015

Wuhan Lotuxs Technology Company, Ltd.
Ms. Wu Na
Regulatory Manager
R&D Building B1 of B, C, D Block, Wuhan National Biological Industry Base
Wuhan, Hubei 430075
People's Republic of China

Re: K142845
Trade/Device Name: SILKPRO Laser Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: May 28, 2015
Received: June 4, 2015

Dear Ms. Na:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142845

Device Name

SILKPRO Laser Hair Removal System

Indications for Use *(Describe)*

SILKPRO is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent hair reduction defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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007_510 (k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

August 24, 2014

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor:	Wuhan Lotuxs Technology Co., Ltd.
Address:	R&D Building B1 of B, C, D Block, Wuhan National Biological Industry Base, No.666 High-tech Avenue, East Lake High-tech Development Zone, Wuhan, P.R.C.
Contact Name:	Wu Na
Telephone No.:	+86-27-87619668
Fax No.:	+86-27-87515058
Email Address:	na.wu@lotuxs.com

3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name:	SILKPRO Laser Hair Removal System
Common Name:	Powered laser surgical instrument
Classification:	878.4810 Laser Instrument, Surgical, Powered
Product code:	OHT
Classification Panel:	General & Plastic Surgery
Device Class:	II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicates within this submission are as follows:

TRIA Beauty, Inc., TRIA Laser Hair Removal System has been cleared by FDA

through 510(k) No.K090820 (Decision Date – Dec 23, 2009),

5. Description of the Device [21 CFR 807.92(a) (4)]

The SILKPRO Laser Hair Removal System emits a pulse of laser light, which heats up the dark pigment inside the hair and deactivates the follicles in the skin that produce hair.

6. Intended Use [21 CFR 807.92(a)(5)]

SILKPRO laser hair removal system adopts the 810nm diode laser, which targets on the hair follicle and slows the process of hair growth. It is used to remove unwanted hair of body. SILKPRO is also intended for permanent hair reduction defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Laser Type	Diode laser
Laser Material	GaAs
Wavelength	810nm
Max Energy Density	25J/cm^2
Energy Density	5J/cm^2、10J/cm^2、15J/cm^2、20J/cm^2、25J/cm^2
Laser Beam	9mm×9mm
Power Capacity	100～240V, 50/60Hz
Electric Parameter	AC100 ~ 240V, 50/60Hz , 60W
Laser Type	Class 4
Working Environment	Ambient Temperature：+5℃～+40℃； relative humidity：≤80%； Atmospheric Pressure: 700_1060hPa
Storage/Transportation environment	Ambient Temperature：-40℃～+55℃； relative humidity：≤90%； Atmospheric Pressure: 700_1060hPa
Weight	700g

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

8.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device SILKPRO	Predicate Device TRIA
1	**Intended Use**	SILKPRO is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.	TRIA is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. TRIA is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime.

8.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device SILKPRO	Predicate Device TRIA
2	**General**		
2.1	Classification Name	Laser Instrument, Surgical, Powered	Laser Instrument, Surgical, Powered
2.2	Product Code	OHT	GEX
2.3	Regulation Number	878.4810	878.4810
2.4	Panel	General & Plastic Surgery	General & Plastic Surgery
2.5	Class	Class II	Class II
3	**Performance**		
3.1	Laser Type	Diode laser	Diode laser
3.2	Laser Material	GaAs	GaAs
3.3	Wavelength	810nm	810nm
3.4	Max Energy Density	25J/cm^2	22J/cm^2
3.5	Energy Density	5J/cm^2, 10J/cm^2, 15J/cm^2, 20J/cm^2, 25J/cm^2	6J/cm^2, 10J/cm^2, 14J/cm^2, 18J/cm^2, 22J/cm^2
3.6	Laser Beam	9mm×9mm	Φ 10mm (Round)
4	**Physical Specifications**		

ID	Comparison Item	Proposed Device SILKPRO	Predicate Device TRIA
Temperature			
4.1	Operating	+5℃～+40℃;	+5℃～+40℃;
4.2	Transport/ Storage	-40℃～+55℃	-40℃～+55℃
Relative humidity			
4.3	Operating	≤ 80%	≤ 80%
4.4	Transport/ Storage	≤ 90%	≤ 90%
Atmospheric Pressure			
4.5	Operating	700_1060hPa	700_1060hPa
4.6	Transport/ Storage	700_1060hPa	700_1060hPa
5	**Power Supply**		
5.1	Power Capacity	AC100～240V, 50/60Hz, 60W	AC100 ～ 240V, 50/60Hz, 37VA
5.2	Input Voltage	100～240V,50/60Hz	100～240V,50/60Hz
6	**Human factors (operation characteristic)**		
6.1	Usability	Button operation	Button operation,
7	**Biocompatibility**		
7.1	Evaluation	Compliance with ISO 10993-1 ISO 10993-5 ISO 10993-10	Compliance with ISO 10993-1 ISO 10993-5 ISO 10993-10
8	**Electrical & Mechanical safety& Thermal safety**		
8.1	Type of protection against electric shock	Class I	Class I
8.2	Degree of protection against harmful ingress of liquid	Ordinary equipment.	Ordinary equipment.
8.3	Evaluation	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard

ID	Comparison Item	Proposed Device SILKPRO	Predicate Device TRIA
		IEC 60601-1.	IEC 60601-1.
9	**Electromagnetic Compatibility**		
9.1	EMC Evaluation	Complying with IEC 60601-1-2	Complying with IEC 60601-1-2

8.4 Discussion of Differences:

It is reasonable that there are some differences between our new device and its predicate. All of parameters comply with 21CFR1020.33 and related IEC standards. We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

Review of ID 1 - Intended use, both are the same, so the SE is not affected.

Review of ID 2 - General, both are the same, so the SE is not affected.

Review of ID 3 - Performance, except three items as below, both are the same, so the SE is not affected.

3.4 Max Energy Density, The proposed device is 25J/cm^2 and the predicate device is 22J/cm^2, both of them comply with IEC 60601-2-22 and IEC 60825-1. Therefore, they can be considered substantially Equivalent in safety and effectiveness. So the SE is not affected.

3.5 Energy Density, The proposed device is 5J/cm^2, 10J/cm^2, 15J/cm^2, 20J/cm^2, 25J/cm^2 and the predicate device is 6J/cm^2, 10J/cm^2, 14J/cm^2, 18J/cm^2, 22J/cm^2, both of them comply with IEC 60601-2-22 and IEC 60825-1. Therefore, they can be considered substantially Equivalent in safety and effectiveness. So the SE is not affected.

3.6 Laser Beam, The proposed device is 9mm×9mm and the predicate device is Φ 10mm (Round), both of them comply with IEC 60601-2-22 and IEC 60825-1. Therefore, they can be considered substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 4 - Physical Specifications, Temperature, Relative humidity and Atmospheric Pressure are comparable, so the SE is not affected

Review of ID 5 - Power Supply, both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 6 - Human factors, both are the same, so the SE is not affected.

Review of ID 7 - Biocompatibility, both are the same, so the SE is not affected.

Review of ID 8 - Electrical & Mechanical safety& Thermal safety, both are the same, so the SE is not affected.

Review of ID 9 - EMC, both are the same, so the SE is not affected.

A Human Factors Usability study was conducted to demonstrate that a layperson was capable of reading the User Manual for the SILKPRO, understood the directions for use, and was able to correctly use the device for the intended use of hair removal as directed in the User Manual. This testing included correct attachment of the power cord, recognizing when the device was activated, correct placement and movement of the device at the targeted site, and understanding of when and where the device was not to be used. There were no failures in terms of correct selection of appropriate site for treatment or correct application of laser to the targeted site.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Wuhan Lotuxs Technology Co., Ltd. concludes that SILKPRO Laser Hair Removal System is substantially equivalent to predicate devices with regard to safety and effectiveness.